K041964

SEP 14 2004

510(k) Summary

Submitter Information:

Mediaid, Inc.
4025 Spencer St., Suite 103
Torrance, CA 90503

Contact:

Mahesh Patel, COO
Telephone: 310-793-8844
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Date Prepared:

July 15, 2004

Product Name:

Common Name: SpO2 Sensor (accessory to pulse oximeter)

Predicate Device:

Mediaid (formerly Palco) currently markets its own pulse oximetry system under K994372 and K911191. Mediaid wishes to extend its product line to include its own brand of pulse oximeter sensors that are compatibile with Nellcor, BCI, and Datex pulse oximeters. Nellcor, BCI, and Datex pulse oximeter sensors are marketed under K863784, K030930, K962156, and K983684, K991823, and K991823.

Description:

Mediaid SpO2 sensors are electro-optical sensors that function without skin penetration, electrical contact, or heat transfer. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The optical components are housed in adhesive film, rigid spring-loaded clip, or foam and Velcro wrap. The sensor cable is terminated in a DB-9 style connector, with an adapter cable for Datex-compatible models.

Intended Use:

Mediaid SpO2 Sensors are indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring.

Comparison to Predicate Device:

Mediaid SpO_2 Sensors use the same theory and principle of operation as the predicate device. Design characteristics are equivalent in terms of safety and effectiveness, as demonstrated by product testing and accuracy claims.

Performance Data & Conclusions:

Performance testing was conducted during clinical hypoxia studies conducted in an independent research lab. Mediaid SpO2 sensors were compared to arterial blood samples analyzed on a laboratory co-oximeter and found to be equivalent to predicate device accuracy claims. Bench testing was performed to verify pulse rate accuracy.

Biocompatibility, electrical safety, and EMC testing was also performed to demonstrate conformance with established industry standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2004

Mediaid, Incorporated
C/O Ms. Krista Oakes
Principal
Amica Solutions
2300 McDermott Road # 200-207
Plano, Texas 75025

Re: K041964
Trade/Device Name: Mediaid SpO2 Sensor
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 10, 2004
Received: September 10, 2004

Dear Ms. Oakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

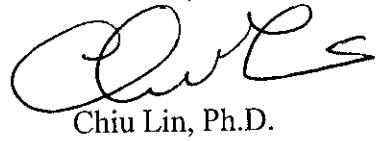
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) # K041964
Device Name: Mediaid SpO2 Sensor

Indications for Use:
The Mediaid SpO2 Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K041964